UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

[UNDER SEAL]	)	No.
Plaintiffs,	)	
v.	)	
	)	
[UNDER SEAL],	)	**FILED UNDER SEAL PURSUANT TO 31 U.S.C. §3730(B)(2)**
Defendants.	)	
	)	**COMPLAINT**

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES, EX REL. DR. SUSAN NEDZA, Relator,	)	NO.
v.	)	**FILED *IN CAMERA* AND UNDER SEAL**
AIM SPECIALTY HEALTH, ANTHEM INC., ANTHEM HEALTH PLANS OF KENTUCKY, INC., ANTHEM HEALTH PLANS OF MAINE, INC., ANTHEM HEALTH PLANS OF NEW HAMPSHIRE, INC., ANTHEM INSURANCE COMPANIES, INC., BLUE CROSS OF CALIFORNIA, BLUE CROSS AND BLUE SHIELD OF GEORGIA, INC., BLUE CROSS OF IDAHO CARE PLUS, INC., BLUE CROSS BLUE SHIELD OF MICHIGAN MUTUAL INSURANCE COMPANY, BLUE CROSS AND BLUE SHIELD OF NORTH CAROLINA, CAMBIA HEALTH SOLUTIONS, INC., CAREMORE HEALTH PLAN OF NEVADA, EMPIRE HEALTHCHOICE ASSURANCE, INC., HEALTH FIRST HEALTH PLANS, INC., HEALTHKEEPERS, INC., MODA HEALTH PLAN, INC., PRIORITY HEALTH, PROVIDENCE HEALTH & SERVICES-OREGON, REGENCE BLUECROSS BLUESHIELD OF OREGON, REGENCE BLUECROSS BLUESHIELD OF UTAH, REGENCE BLUESHIELD, AND REGENCE BLUE SHIELD OF IDAHO.	)	JURY TRIAL DEMANDED
Defendants.	)	COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIM ACT

COMPLAINT

Dr. Susan Nedza, both on behalf of the United States and herself individually, complains, by counsel, against AIM Specialty Health, Anthem Inc.,

Anthem Health Plans of Kentucky, Inc., Anthem Health Plans of Maine, Inc., Anthem Health Plans of New Hampshire, Inc., Anthem Insurance Companies, Inc., Blue Cross of California, Blue Cross and Blue Shield of Georgia, Inc., Blue Cross of Idaho Care Plus, Inc., Blue Cross Blue Shield of Michigan Mutual Insurance Company, Blue Cross and Blue Shield of North Carolina, Cambia Health Solutions, Inc., CareMore Health Plan of Nevada, Empire HealthChoice Assurance, Inc., Health First Health Plans, Inc., HealthKeepers, Inc., Moda Health Plan, Inc., Priority Health, Providence Health & Services-Oregon, Regence BlueCross BlueShield of Oregon, Regence BlueCross BlueShield of Utah, Regence BlueShield, and Regence Blue Shield of Idaho (collectively, Defendants") as follows:

NATURE OF THE ACTION

1. This is a civil action by the United States, through Relator-Plaintiff Dr. Susan Nedza ("Relator" or "Nedza"), to recover treble damages and civil penalties arising from violations of the False Claims Act, 31 U.S.C. §§ 3729-3733, by Defendants AIM Specialty Health ("AIM"), its parent company, Anthem Inc. ("Anthem"), as well as its clients ("Client Health Insurance Plans"), including Anthem Health Plans of Kentucky, Inc., Anthem Health Plans of Maine, Inc., Anthem Health Plans of New Hampshire, Inc., Anthem Insurance Companies, Inc., Blue Cross of California, Blue Cross and Blue Shield of Georgia, Inc., Blue Cross of Idaho Care Plus, Inc., Blue Cross Blue Shield of Michigan Mutual Insurance Company, Blue Cross and Blue Shield of North Carolina, Cambia Health Solutions, Inc., CareMore Health Plan of Nevada, Empire HealthChoice Assurance, Inc.,

Health First Health Plans, Inc., HealthKeepers, Inc., Moda Health Plan, Inc., Priority Health, Providence Health & Services-Oregon, Regence BlueCross BlueShield of Oregon, Regence BlueCross BlueShield of Utah, Regence BlueShield, and Regence Blue Shield of Idaho.

2. These false claims arise from Defendants and/or their agents and employees (a) knowingly causing to be presented false or fraudulent claims for payment or approval to the Government; and (b) knowingly making, using or causing to be made or used false records or statements to get false or fraudulent claims approved by the Government.

3. AIM is a specialty health benefits management corporation that makes health insurance coverage determinations in the areas of radiology, cardiology, oncology, specialty drugs, and sleep medicine on behalf of its clients, private health insurance plans. AIM has developed and employs its own medical appropriateness utilization guidelines that it uses to determine whether a beneficiary of its Client Health Insurance Plans should receive coverage for a particular service. Based on its guidelines, AIM issues a recommendation to its Client Health Insurance Plan to approve or deny a claim. These recommendations are adopted, generally without review, by the Client Health Insurance Plan in denying or approving coverage of the claim.

4. AIM provides value to its Client Health Insurance Plans by taking on the task of making coverage determinations and increases their profit margins by denying claims AIM deems "medically unnecessary" according to its own internal

guidelines. AIM provides its clients with periodic calculations of the savings they have enjoyed as a result of using AIM's services.

5. AIM's Client Health Insurance Plans participate in Medicare Advantage ("MA"), a government program in which the federal government contracts with private health insurance plans to provide and administer insurance coverage for Medicare-eligible individuals. By participating in the Medicare Advantage program, and thus accepting government funds to provide coverage to Medicare recipients, AIM's Client Health Insurance Plans have agreed to abide by the rules and policies meant to protect both Medicare beneficiaries and the federal government, ensuring that health coverage is consistent with the Medicare program, and protecting against inappropriate, fraudulent and wasteful use of taxpayer funds. Among the most essential of these rules and policies are those that determine the extent and level of coverage to which beneficiaries are entitled under the Medicare program.

6. Since 2008 or earlier, AIM has made coverage determinations on behalf of its Client Health Insurance Plans participating in the MA program in cases involving Medicare recipients. AIM has done so in violation of the policies, rules, and regulations governing the Medicare Advantage program ("Medicare Guidelines"), as set forth by the Center for Medicare and Medicaid Services ("CMS") and Congress. Specifically, the Medicare Guidelines pertaining to coverage determinations include CMS's National Coverage Determinations ("NCDs"), 42 U.S.C. § 1395ff(f)(1)(B); 42 U.S.C. § 1395y; 42 C.F.R. § 422.100, and Local Coverage

Determinations ("LCDs"), which are regional coverage guidelines authored by Medicare Administrator Contractors ("MACs") that contract with CMS to oversee the administration of the MA program in a particular geographic area. 42 U.S.C. § 1395ff(f)(2)(B).

7. Instead, AIM has issued coverage determinations based on its own stringent clinical guidelines that have the purpose and effect of regularly delaying or denying medical services to which Medicare beneficiaries are legally entitled under the Medicare program and according to Medicare Guidelines. AIM has done this knowing that it violates Medicare Guidelines, and in order to increase its own profit and the profit margins for its Client Health Insurance Plans.

8. AIM's Client Health Insurance Plans have outsourced a fundamental obligation under the Medicare program – determination of proper coverage – to AIM. These Client Health Insurance Plans have benefitted from AIM's restrictive coverage determinations made in violation of Medicare Guidelines. In turn, AIM has benefitted by retaining and expanding its client base. As a result, the profits of both AIM and of AIM's Client Health Insurance Plans have far exceeded the profits they would have enjoyed had they abided by the Medicare Guidelines. Many of AIM's Client Health Insurance Plans knowingly engaged in this unlawful behavior while others wholly ceded to AIM their obligations to the federal government to provide lawful Medicare coverage without ensuring that they were meeting their responsibilities as contractors with CMS.

9. As a result of AIM's misconduct, the federal government pays out approximately $10 billion each year to AIM's Client Health Insurance Plans for Medicare Advantage beneficiaries, and indirectly to AIM, to administer the Medicare Advantage program, paying monies for non-compliant coverage to approximately one million Medicare beneficiaries.

10. In exchange for government funds and in an effort to increase their own profits, Defendants AIM and Anthem have systematically engaged in conduct with the intent and effect of providing substandard coverage to Medicare beneficiaries and have caused and cooperated with their Client Health Insurance Plans to present fraudulent claim for payment or approval to the Center for Medicare and Medicaid Services. As a consequence, Medicare beneficiaries have often been forced to endure unnecessary delays in the receipt of needed services, the worsening of their conditions prior to diagnosis, and long periods of unnecessary physical pain, and have been denied necessary healthcare. Relator thus brings this case to the governments' attention to address this grave and disturbing wrongful use of government money and abuse of Medicare participants.

PARTIES

11. Nedza served as Chief Medical Officer and a member of the executive team at AIM from July 2012 until January 2015. In that position, Nedza was responsible for the development and enhancement of clinical appropriateness criteria used by Client Health Insurance Plans in making coverage determinations.[1]

[1] Evidence-based clinical appropriateness criteria are criteria based upon national guidelines and scientific evidence that are used to determine whether a particular

Among other things, Nedza oversaw the Clinical Affairs Group and was responsible for development of clinical guidelines and regulatory compliance for Medicare and Medicaid programs, including compliance with Medicare policies and regulations.

12. Prior to her position at AIM, Nedza was Vice President of Strategic Clinical Solutions at Health Circles, LLC, where she served as a member of the executive team and led the clinical team that built evidence-based clinical tools for healthcare providers.[2] From 2008 to 2010, she was Vice President and Clinical Quality and Patient Safety Strategy Medical Director at the American Medical Association. And from 2003 to 2008, Nedza served as the Chief Medical Officer and Medical Officer in the Special Program Office in the U.S. Department for Health and Human Services at the Center for Medicare and Medicaid Services. Among her duties was the responsibility for improving the Medicare claims processing infrastructure.

13. Nedza holds an M.B.A. from the Kellogg Graduate School of Management of Northwestern University and an M.D. from the Stritch School of Medicine at Loyola University.

14. Defendant AIM is a specialty health benefits management corporation organized under the laws of the state of Illinois. AIM is a wholly-owned subsidiary of Anthem. AIM makes health insurance coverage determinations in the areas of

---

medical benefit is clinically appropriate and, as a result, will be covered as medically necessary by a plan.

[2] Evidence-based clinical tools are clinical algorithms that enable doctors to effectively and efficiently manage patient care.

radiology, cardiology, oncology, specialty drugs, and sleep medicine for over 48 health plans with approximately 38 million covered members.

15. Defendant Anthem (formerly known as WellPoint) is a health benefits company organized under the laws of the state of Indiana. Anthem is AIM's parent company; one of AIM's clients; and is the parent company of National Government Services, which is one of the MACs that authors regional guidelines regarding Medicare compliance.

16. Anthem serves approximately 68 million individuals through its affiliated companies, including more than 36 million individuals enrolled in one of its health insurance plans. One in nine Americans receives coverage for their medical care through Anthem's affiliated plans.

17. The Client Health Insurance Plans, including Anthem Health Plans of Kentucky, Inc., Anthem Health Plans of Maine, Inc., Anthem Health Plans of New Hampshire, Inc., Anthem Insurance Companies, Inc., Blue Cross of California, Blue Cross and Blue Shield of Georgia, Inc., Blue Cross of Idaho Care Plus, Inc., Blue Cross Blue Shield of Michigan Mutual Insurance Company, Blue Cross and Blue Shield of North Carolina, Cambia Health Solutions, Inc., CareMore Health Plan of Nevada, Empire HealthChoice Assurance, Inc., Health First Health Plans, Inc., HealthKeepers, Inc., Moda Health Plan, Inc., Priority Health, Providence Health & Services-Oregon, Regence BlueCross BlueShield of Oregon, Regence BlueCross BlueShield of Utah, Regence BlueShield, and Regence Blue Shield of Idaho, are

clients of AIM that offer health insurance coverage to Medicare beneficiaries through the MA program.

18. Defendant Client Health Insurance Plans contract with AIM to make coverage determinations for their approximately one million Medicare beneficiaries. In total, Client Health Insurance Plans receive approximately $10 billion per year in payments from the federal government under the Medicare Advantage program to provide Medicare-compliant coverage. The Client Health Insurance Plans are required to provide benefits and coverage subject to the Medicare Guidelines.

19. When Client Health Insurance Plans participating in the MA program receive payment from the federal government for providing Medicare coverage, the payments are subject to the requirements of the False Claims Act.

20. As described in this complaint, AIM, its parent company, Anthem, and Defendant Client Health Insurance Plans violated the False Claims Act ("FCA") repeatedly and knowingly by: (a) causing false or fraudulent claims to be presented to the Government for payment or approval; and (b) causing false statements or records, material to a false or fraudulent claim, to be made or used.

JURISDICTION AND VENUE

21. This court has jurisdiction over the subject matter of this action pursuant to: (i) 31 U.S.C. § 3732, which confers jurisdiction for claims brought to enforce the False Claims Act; (ii) 28 U.S.C. § 1331, which confers general federal question jurisdiction; and (iii) 28 U.S.C. § 1345, because the United States is a plaintiff.

22. Venue is proper in this district under 31 U.S.C. § 3732(a) because AIM transacts business in this district and committed a number of the acts complained of in this district.

23. This suit is not based on prior public disclosures of allegations or transactions in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; in a congressional, Government Accounting Office or other Federal report, hearing, audit, or investigation, or from the news media; and to any extent there may have been prior public disclosure, Nedza is an original source of the information, who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing this action.

24. Nedza has direct and independent knowledge of the information on which this complaint is based and, before filing this complaint, Nedza provided a statement summarizing substantially all known material evidence and information she possessed related to this Complaint to the United States Attorney for the Northern District of Illinois, in accordance with 31 U.S.C. § 3730(b)(2).

FACTUAL ALLEGATIONS

I. Regulatory Background and Framework

25. The Medicare Advantage program was established by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which amended the Social Security Act, 42 U.S.C. Chapter 7, in an effort to reduce the administrative burden of the Medicare program on the federal government. The

Medicare Advantage program provides an alternative to the traditional Medicare fee-for-service program, allowing beneficiaries to receive Medicare benefits through programs administered by private health insurance plans. Under Medicare Advantage, the federal government contracts with private health insurance plans to provide health care coverage to eligible beneficiaries. By subcontracting much of the administrative burden as well as claims processing, the Medicare Advantage program was intended to increase the efficiency of the Medicare program, allowing for greater portions of government funds to be spent on providing beneficiaries with comprehensive quality care.

26. CMS, which is a division of the U.S. Department for Health and Human Services, compensates participating private health insurance plans through flat monthly payments called "capitation" payments for each Medicare beneficiary. CMS calculates capitation payments by determining a base rate, also termed a "benchmark," that reflects the cost of insuring an average beneficiary in the plan's geographic region. Any cost the private health insurance plan incurs above the capitation payment must be absorbed by the plan or, may be charged to the beneficiary as a premium if agreed upon with CMS at the time of application. During the application process, private health insurance plans submit bids that represent their estimated cost for insuring a Medicare beneficiary as well as administrative costs and a margin for profit.

27. CMS accepts all bids that meet its basic program requirements and then calculates the capitation payment for the private health insurance plan based

on the benchmark that is slightly adjusted depending on the quality ratings for each plan. The better quality plans receive a higher capitation payment than the lower quality plans. CMS assigns quality ratings based on a number of factors, including customer service ratings and customer complaints, successful appeals, and preventative services and tests offered. If the plan's bid falls above the calculated benchmark, CMS may allow the plan to charge beneficiaries the difference through a monthly premium. If the plan's bid falls below the benchmark, the plan must use the remainder to improve services for the beneficiary. The capitation fee received by the plan is then adjusted for beneficiaries with high risk scores that are likely to require a higher level of benefits than the mandatory basic benefits. 42 U.S.C. § 1395w-23(a)(3).

A. Protections for Beneficiaries and Contractual Obligations of Private Health Insurance Plans

28. To ensure that beneficiaries receive proper health insurance coverage through Medicare Advantage, CMS issues Medicare Guidelines, which, as described above, are regulations and guidelines on the structure and implementation of Medicare Advantage plans that participating private health insurance plans must follow. CMS also has a monitoring program to ensure compliance with Medicare Guidelines. Plans that fail to abide by these legal and contractual obligations may be suspended, discontinued, sanctioned, or fined. 42 C.F.R. § 423.750.

29. The primary duty of a private health insurance plan participating in Medicare Advantage is to provide beneficiaries with the basic services and benefits required under the Medicare program. Plans are required to provide all services and

benefits that are "medically necessary," as defined by CMS regulations and guidelines. 42 U.S.C. § 1395w–27(g)(1). Participating plans must sign a contract with the federal government that guarantees the provision of these basic benefits to beneficiaries as well as obligates establishment of procedures and compliance mechanisms aimed at preventing fraud and abuse.

30. Specifically, to ensure compliance, the contract with CMS requires participating plans to agree to: (a) provide basic Medicare benefits and abide by Medicare Guidelines in making any coverage determinations (42 C.F.R. § 422.504(a)); (b) develop a timely procedure for making those determinations (42 C.F.R. § 422.566(a)); and (c) set up and implement an effective compliance program that ensures coverage determinations are made in accordance with CMS guidelines (42 C.F.R. § 422.503).

31. Private health insurance plans must provide all benefits consistent with the Medicare program and agree to comply with the Medicare Guidelines in making benefit coverage determinations. 42 C.F.R. § 422.504(a); 42 CFR § 422.100 (a). Beneficiaries are entitled to coverage of all Medicare basic benefits and access to those benefits. 42 C.F.R. § 422.504(a)(3)(i)-(iii).

32. Private health insurance plans must also have effective procedures in place to make proper determinations of Medicare benefits coverage. 42 C.F.R. § 422.566(a). Procedures must exist to make determinations of basic benefits covered by Medicare, including review of refusals by the plan to pay for services that a beneficiary believes should be covered and any failure by the plan to approve health

care services in a timely manner such that the delay "adversely affect[s] the health of the enrollee." 42 C.F.R. § 422.566(b). Whenever the plan expects to issue a "partially or fully adverse medical necessity decision," it must be reviewed by a physician familiar with "Medicare coverage criteria" before such a decision is issued. 42 C.F.R. § 422.566(d).

33. The private health insurance plan must also "adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse."42 C.F.R. § 422.503(b)(vi). Such a compliance program is a requirement to eligibility for a contract with CMS. *Id.* An effective compliance program must include conducting routine monitoring, audits, and timely and reasonable inquiries when non-compliance is discovered; taking corrective actions when necessary; and voluntarily self-reporting fraud and misconduct. 42 C.F.R. § 422.503(b)(4)(vi)(A)-(G). The plan must also comply with all requirements governing grievances by beneficiaries and appeals of coverage denials. 42 C.F.R. § 422.504(a)(7).

B. Determining the Basic Benefits Due to Beneficiaries Under Medicare

34. The Social Security Act and subsequent amendments entitle Medicare beneficiaries to health care services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" and in some cases reasonable and necessary for the prevention of illness. 42 U.S.C. § 1395y(a)(1)(A)-(B). The definition of "reasonable

and necessary" is determined by CMS through reference to "(1) published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and (2) general acceptance by the medical community as supported by sound medical evidence." Medicare Program Integrity Manual § 13.7.1 (2014).

35. CMS provides direction on Medicare coverage through NCDs. NCDs address whether particular items or services are covered by Medicare. 42 U.S.C. § 1395y, 1395ff; 42 C.F.R. § 422.100. Where an NCD exists regarding Medicare coverage, private insurance plans participating in the Medicare program are required to comply with the NCD. 42 CFR § 422.101(b)(1). The only exception to compliance with an NCD is where a revised NCD results in a "significant cost" increase that exceeds the negotiated payment under an existing contract. 42 C.F.R. § 422.109. In such circumstances, CMS may make an exception under the existing contract, but only upon petition of the private health insurance plan, and will require the health plan to comply with the revised NCD the following contract year.

36. Participating private health insurance plans must also comply with LCDs. LCDs are regional coverage guidelines authored by Medicare Administrator Contractors ("MAC") that contract with CMS to oversee the administration of the Medicare Advantage program in a particular geographic area. *Id.* LCDs provide a greater level of detail of which services and benefits will be covered by MA in certain areas. 42 C.F.R. § 422.101(b)(3). An LCD is "a determination by a fiscal

intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section § 1862(a)(1)(A)." 42 U.S.C. § 1395ff(f)(2)(B). According to CMS, an LCD reflects the intermediary's determination of reasonable and necessary conditions of coverage as allowed under § 1862(a)(1)(A) of the Act.[3] LCDs "specify under what clinical circumstances an item or service is considered to be reasonable and necessary." § 13.1.3 of the Medicare Program Integrity Manual.

II. False Claims Arising from AIM's Failure to Abide by NCDs and LCDs in Making Coverage Determinations.

A. AIM's role in making coverage determinations for defendant client health insurance plans and, as a result, Medicare beneficiaries

37. The service Defendant AIM provides to Defendant Client Health Insurance Plans is straightforward: AIM receives a request for coverage from the provider, such as the treating doctor, makes the determination of whether or not the request should be covered by the plan, and communicates with the plan and/or the Medicare Advantage beneficiary its determination of whether the request should be approved, denied, or redirected (to another service or delayed until other measures are taken). Among others, AIM determines whether the private health insurance plans should approve the following: Computerized Tomography (CT) scans,

[3] CMS.gov, Medicare, Local Coverage Determinations, http://www.cms.gov/Medicare/Coverage/DeterminationProcess/LCDs.html (last visited July 7, 2015).

Echocardiography, Magnetic Resonance Angiograms (MRA), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET scan), and sleep studies. With few exceptions, Defendant Client Health Insurance Plans merely adopt AIM's recommendation and approve, deny or redirect the claim accordingly.

38. The coverage determinations that AIM conducts for its Client Health Insurance Plans are essential to their clients' contractual obligations with the federal government as Medicare Advantage contractors. Because its Client Health Insurance Plans with government contracts must provide coverage that is consistent with Medicare, AIM is responsible for implementing a key aspect of its clients' obligation as a participant in the Medicare Advantage program.

B. AIM's failure to comply with NCDs and LCDs in making coverage determinations for Medicare beneficiaries and Defendant Client Health Insurance Plans' failure to comply with applicable Medicare Guidelines.

39. Starting in at least 2008, AIM has made coverage determinations with almost complete disregard for NCDs and LCDs, causing its Client Health Insurance Plans to knowingly submit false claims to the government in service of increasing their own profit. Instead, AIM has consistently relied upon its own guidelines, AIM's Clinical Appropriateness Guidelines ("AIM Guidelines"), rather than the Medicare-mandated NCDs and LCDs, to make coverage determinations.

40. AIM, with Anthem's knowledge, relied upon its own Clinical Appropriateness Guidelines to determine coverage for Medicare beneficiaries. AIM and Anthem relied upon the AIM Guidelines despite their knowledge of the lack of compliance with the applicable NCDs or LCDs, concluding that most NCDs lacked

any clinical value and that the LCDs were merely administrative/coding guidance for providers.

41. Where there were inconsistencies between AIM's Guidelines and the NCDs or LCDs, AIM followed its own Guidelines that construed coverage more narrowly. AIM did so in order to create significant cost-savings to its clients, the private health insurance plans, and in order to increase its own profits. In turn, Medicare beneficiaries were deprived of significant Medicare benefits and subjected to lower standards of care.

42. AIM had two primary methods for making its determination as to whether or not the request should be covered by the Client Health Insurance Plan: (1) a utilization management system in which AIM only approved services that were in compliance with AIM Guidelines; (2) a utilization management system in which AIM encouraged the withdrawal or redirection of services that were not in compliance with AIM Guidelines. The Client Health Insurance Plans did not routinely communicate to treating physicians which utilization management system AIM was using in reviewing the requests. Regardless which utilization management system AIM was using, AIM was relying upon the AIM Guidelines in making its decisions rather than the Medicare Guidelines.

43. After reviewing the request for healthcare from non-Anthem Client Health Insurance Plans, AIM issued a Notice of Denial of Medical Coverage, which it sent directly to the Medicare Advantage beneficiary, in which it regularly cited to an NCD or LCD as a basis for denying the request but cited language from the AIM

Guideline, which was not in compliance with Medicare Guidelines, in support of that decision. For Anthem Client Health Insurance Plans, Anthem sent a Notice of Denial of Medical Coverage to the beneficiary, in which it also cited to an NCD or LCD as a basis for denying the request but cited the AIM Guidelines in the denial rationale, which was not in compliance with Medicare Guidelines, in support of that decision.

44. As a result of AIM's actions, AIM's Client Health Insurance Plans repeatedly and regularly denied Medicare beneficiaries coverage for services that should have been approved under NCDs and LCDs. AIM's practice denied Medicare beneficiaries services to which they were entitled and allowed AIM's Client Health Insurance Plans savings of approximately $19 million in 2014 alone in advanced imaging costs they would have incurred had they abided by their contractual obligations with the federal government. AIM provided its Client Health Insurance Plans with "value statements" each year to demonstrate the documented cost-savings that resulted from reliance on AIM Guidelines as opposed to the Medicare Guidelines.

45. AIM Guidelines created artificial barriers to diagnosis as well outright claim denials and unnecessary diagnostic delays that lead to prolonged and sustained periods of pain and suffering for beneficiaries, and allowed its clients to charge multiple co-pays to beneficiaries for testing requests that should have been approved in a single claim. The following are some examples of imaging benefits that were denied or redirected under AIM Guidelines:

a. Denying requests for CT scans where such scans would have been medically appropriate under Medicare Guidelines;

b. Requiring an X-ray to be performed prior to approving a request for an imaging benefit where no such prerequisite existed under Medicare Guidelines;

c. Requiring physical therapy prior to approving an imaging request where no such requirement existed under Medicare Guidelines;

d. Denying requests for imaging of adjacent sites where no such limitations exists under Medicare Guidelines; and

e. Denying requests for bilateral imaging where no such limitation exists under Medicare Guidelines.

46. In light of the fact that the government paid the Client Health Insurance Plans on a flat rate (i.e. the capitation rate) to provide all benefits allowed under the Medicare Guidelines, the Client Health Insurance Plans increased their profits by limiting approval of more costly benefits, in violation of their contractual obligations.

47. Proper reliance on NCDs and LCDs results in a claim denial rate of approximately 0.5%. In contrast, according to AIM's internal estimates in 2013, adherence to the AIM Guidelines in this manner over the NCDs and LCDs resulted in a claim denial rate of approximately 7 to 9% of advanced imaging requests, which include requests for CT scans, Echocardiography, MRA scans, MRI, and PET scans.

In fact, the use of improper criteria may have had even greater negative impact. In 2013, AIM staff reviewed 164 non-cardiac cases that AIM had denied in reliance on AIM Guidelines and determined that 160 should have been approved under the NCDs or LCDs, meaning only four of the non-cardiac cases, or 2.5%, had been properly denied.

48. AIM's internal communications and documentation reflect a complete and conscious disregard for NCDs and a lack of understanding of their Client Health Insurance Plans' obligations to abide by LCDs. AIM executives knowingly implemented this unlawful practice to further their own business interests, refusing to employ coverage determinations that would comply with Medicare requirements. AIM's primary goal was to save its Client Health Insurance Plans money in order to preserve them as clients.

49. AIM executives treated compliance with Medicare regulations as an optional business decision and something that would decrease profits for its Client Health Insurance Plans. AIM executives recognized the tension between its Client Health Insurance Plans' business decision makers and compliance decision makers decision in balancing profit against compliance risk.

50. As a result of AIM's failure to comply with Medicare Guidelines, CMS audits resulted in findings that some of AIM's Client Health Insurance Plans were out of compliance. In response, AIM began to offer its Client Health Insurance Plans alternate models for assessing coverage, reflecting varying levels of compliance with Medicare-mandated NCDs and LCDs. AIM termed these models

"products;" the products would allow its Client Health Insurance Plans to choose the level of Medicare-compliant review that AIM would conduct.

51. AIM continued to offer review in which it relied solely on its own non-compliant Guidelines as a "product" with additional savings. AIM executives believed that some of its Client Health Insurance Plans that had not been subject to CMS audits might prefer to have AIM continue to utilize a non-compliant model. AIM executives recognized that a review with a non-compliant model had the potential to impact the Medicare Star Ratings for its Client Health Insurance Plans as a result of the high risk of appeals.

52. Executives in the compliance department at AIM and Anthem were well aware that AIM's non-compliance with NCDs and LCDs was in violation of Medicare rules and regulations. AIM executives openly discussed how its noncompliance with Medicare regulations could have ramifications for its Client Health Insurance Plans, including potentially facing criminal charges or being barred from MA Program.

53. On several occasions, Dr. Julie Thiel, AIM's Vice President of Clinical Operations and later Senior Vice President of Clinical Programs, urged that AIM had to stop inappropriately denying medical services in conducting its review for its Client Health Insurance Plans.

54. In another acknowledgment of its reliance upon non-compliant guidelines, in October 2014, AIM considered revising its contracts with Client

Health Insurance Plans to indicate that AIM was not responsible for their violations of Medicare Guidelines.

55. Despite AIM's failure to comply with the Medicare Guidelines, AIM charged its Medicare Advantage Client Health Insurance Plans three times the amount for its services than it charged its commercial Client Health Insurance Plans with the purported justification of the additional compliance costs that were incurred for Medicare Advantage plans.

56. By engaging in non-compliant coverage determinations on behalf of its Client Health Insurance Plans offering MA coverage, AIM and Anthem caused these plans to repeatedly present false or fraudulent claims for payment or approval to the federal government in violation 31 U.S.C. §§ 3729(a)(1)(A).

57. Moreover, by inducing its Client Health Insurance Plans to misrepresent to the government the compliant nature of its program, Anthem and AIM repeatedly and knowingly made or used or caused false statements or records to be made or used material to a false or fraudulent claim in violation of 31 U.S.C. §§ 3729(a)(1)(B) .

58. Similarly, AIM's Client Health Insurance Plans either knew or reasonably should have known of the non-compliant coverage determination program AIM was implementing on their behalf. In fact, some of AIM's Client Health Insurance Plans, such as BCBS of Michigan and North Carolina, gave AIM explicit permission to only rely on AIM Guidelines instead of the NCDs and LCDs in order to increase their profit margins.

59. By failing to provide coverage required under the MA program, AIM's Client Health Insurance Plans repeatedly presented false or fraudulent claims for payment or approval to the federal government in violation 31 U.S.C. §§ 3729(a)(1)(A) and repeatedly and knowingly made or used or caused false statements or records to be made or used material to a false or fraudulent claim in violation of 31 U.S.C. §§ 3729(a)(1)(B) .

COUNT I
(Violations of 31 U.S.C. §§ 3729(a)(1)(A))

60. Relator-Plaintiff repeats and re-alleges paragraphs 1-50.

61. This Count is brought by Nedza in the name of the United States under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendants' violations of 31 U.S.C. §§ 3729(a)(1)(A).

62. By virtue of the acts described above, among others, Defendants repeatedly knowingly presented, or caused to be presented, false or fraudulent claim for payment or approval to the Center for Medicare and Medicaid Services.

63. By virtue of the acts described above, among others, Defendants has violated the False Claims Act by repeatedly and knowingly presenting or causing false or fraudulent claims to be presented to the Government for payment or approval.

64. Plaintiff United States, unaware of the falsity of the claims and/or statements or records, and in reliance on their accuracy, paid for claims that would otherwise not have been allowed.

65. The amounts of the false or fraudulent claims to the United States were material.

COUNT II
(Violations of 31 U.S.C. §§ 3729(a)(1)(B))

66. Relator-Plaintiff repeats and re-alleges paragraphs 1-56.

67. This Count is brought by Nedza in the name of the United States under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendants' violations of 31 U.S.C. §§ 3729(a)(1)(B).

68. By virtue of the acts described above, among others, Defendants repeatedly and knowingly made or used or caused false statements or records to be made or used material to a false or fraudulent claim.

69. Plaintiff United States, unaware of the falsity of the claims and/or statements or records, and in reliance on their accuracy, paid for claims that would otherwise not have been allowed.

70. The amounts of the false or fraudulent claims to the United States were material.

PRAYER FOR RELIEF

WHEREFORE, Relator prays for entry of judgment awarding the following damages or relief to the following parties and against AIM:

To the UNITED STATES GOVERNMENT:

1. Three times the amount of actual damages sustained by the United States Government.

2. A civil penalty of not less than $5,500 and not more than $11,000 for each false claim AIM submitted to the United States Government, or a greater amount if allowed by law;

3. Prejudgment interest and all other applicable interest;

4. Expert witness fees; and

5. All other costs of this action.

To the RELATOR:

1. The maximum amount allowed under 31 U.S.C. § 3730(d);

2. The maximum relief allowed under 31 U.S.C. § 3730(h)(2), including but not limited to reinstatement with full seniority status, or front pay, two times back pay, interest on back pay, and compensation for special damages;

3. Punitive damages.

4. Reimbursement of all costs and expenses Relator incurs in connection with this action;

5. Reasonable attorneys' fees;

6. Expert witness fees;

6. All other costs of this action; and

7. All further relief the Court deems just and proper.

JURY DEMAND

Relator requests a jury trial on all claims that can be tried to a jury.

Dated: August 7, 2015

By: Steven Cohen

One of the Attorneys for
Relator-Plaintiff
Dr. Susan Nedza

Steven Cohen
COHEN LAW GROUP
70 West Madison Street, Suite 4000
Chicago IL 60602
scohen@cohenlawgroup.com
312.327.8800

Matthew J. Piers
Juliet Berger-White
HUGHES SOCOL PIERS
RESNICK & DYM, LTD.
70 W. Madison Street, Suite 4000
Chicago, IL 60602
mpiers@hsplegal.com
jberger-white@hsplegal.com
312.580.0100

CERTIFICATE OF SERVICE

The undersigned, attorney for Plaintiff-Relator, certifies that she caused a true and correct copy of the attached Relator's Complaint under seal to be served on counsel identified below, at the addresses and by the means specified below, on this 7th day of August 2015.

TO: Loretta Lynch, Attorney General of the United States
Attention: Michael Granston, Director, Civil Division, Civil Fraud Section
United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, D.C. 20530
By Certified Mail

United States Attorney for the Northern District of Illinois
Attention: AUSA Linda Wawzenski
219 South Dearborn Street, Fifth Floor
Chicago, Illinois 60604
By Messenger Delivery

/s/ Juliet Berger-White
Juliet Berger-White
One of the Attorneys for the Relator-Plaintiff

Matthew J. Piers
ARDC IL# 2206161
Juliet Berger-White
ARDC IL#6269404
HUGHES SOCOL PIERS
RESNICK & DYM, LTD.
70 W. Madison Street, Suite 4000
Chicago, IL 60602
mpiers@hsplegal.com
jberger-white@hsplegal.com
312.580.0100

Steven Cohen
COHEN LAW GROUP
ARDC#3124146
70 West Madison Street, Suite 4000
Chicago IL 60602
scohen@cohenlawgroup.com
312.327.8800

UNITED STATES DISTRICT COURT
NORTHERN I[illegible]
EAST[illegible]

United States *ex rel* Dr. Susan Nedza

Plaintiffs,

v.

AIM Specialty Health, et al

Defendant.

Castillo

FILED *IN CAMERA* AND UNDER SEAL

JURY TRIAL DEMANDED

NOTICE OF FILING COMPLAINT UNDER SEAL

Pursuant to Local Rule 5.7 of the United States District Court for the Northern District of Illinois, the undersigned, Juliet Berger-White, states as follows:

1. The complaint contained herein is filed under seal pursuant to 31 U.S.C. § 3730.

2. Unless otherwise ordered by the Court, the matter shall remain restricted for sixty days, the period specified in 31 U.S.C. § 3730.

3. The Plaintiff-Relator is aware that absent an order extending or setting aside the sealing, the file and its contents will become public once the period specified in 31 U.S.C. § 3730 elapses.

Dated: August 7, 2015

Respectfully submitted,

Juliet Berger-White
One of the Attorneys for the Relator-Plaintiff

Matthew J. Piers
ARDC IL# 2206161
Juliet Berger-White
ARDC IL#6269404
HUGHES SOCOL PIERS
RESNICK & DYM, LTD.
70 W. Madison Street, Suite 4000
Chicago, IL 60602
mpiers@hsplegal.com
jberger-white@hsplegal.com
312.580.0100

Steven Cohen
COHEN LAW GROUP
ARDC#3124146
70 West Madison Street, Suite 4000
Chicago IL 60602
scohen@cohenlawgroup.com
312.327.8800